K012429

NOV 0 6 2001

510(k) Summary

1. **Name/Address of Submitter:** Applied Diabetes Research, Inc.
   1740 South IH 35E
   Suite 112
   Carrollton, TX 75006

2. **Contact Person:** George R. Lynch
   President
   (800) 746-7505
   (972) 446-8406

3. **Date Summary Prepared:** July 16, 2001

4. **Device Name:** SmartSet Insulin Infusion Device

5. **Predicate Devices:** MiniMed Sof-Set Micro QR Infusion Set (K991979)

6. **Device Description and Intended Use:** The SmartSet Insulin Infusion Device is intended for the subcutaneous infusion of medicine, including insulin, from an external infusion pump. Its introducer needle is inserted at a right angle into the subcurtaneous tissue of the infusion site and then withdrawn to leave the indwelling catheter in place. The pump end of the Smart-Set tubing is attached to an external infusion pump. Following the pump manufacturer's instructions, the tubing is primed until medication drips from the connector needle. The SmartSet end of the tubing is aligned with the SmartSet hub and then firmly locked together.

7. **Brief Description of Nonclinical and Clinical Testing:** Appropriate information relative to the biocompatibility of the device's components and the sterilization of the finished device, but not clinical study findings, were submitted.

8. **Conclusions Drawn:** The intended use of the SmartSet Insulin Infusion Device is identical to that of the cited predicate device. Any differences in technological characteristics were insignificant and do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 6 2001

Applied Diabetes Research, Incorporated
C/O Mr. Charles H. Kyper
Kyper & Associates
103 Nolen Lane
Church Hill, North Carolina 27516

Re: K012429
Trade/Device Name: Sureset Infusion Set, Model 8023
Regulation Number: 880.5440
Regulation Name: FPA Set, Administration, Intravascular
Regulatory Class: II
Product Code: FPA
Dated: August 28, 2001
Received: August 29, 2001

Dear Mr. Kyper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 0 6 2001

Indication for Use

510(k) Number (if known): K012429

Device Name:

Indication for Use: **Intended for the subcutaneous infusion of medicine, including insulin, from an external infusion pump**

Concurrence of CDRH Office of Device Evaluation

Prescription Use ✓ **OR** **Over-the-counter Use** ____
(per 21 CFR 801.109)

Patricia Cicenia

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K012429